IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

| In re Application of: K. Miyazawa, et al. |) | Examiner: R. Loewe |
|--|---|-------------------------|
| Serial No.: 10/534,399 |) | Group Art Unit: 1796 |
| Filed: May 10, 2005 |) | Docket: TOS-162-USA-PCT |

For: Polysiloxane Having Phosporylcholine Group And Process For Producing The Same

APPELLANT'S REPLY BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir: The undersigned respectfully replies in the above-identified application to the Examiner's Answer mailed on December 8, 2008.

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I. STATUS OF THE CLAIMS

- 1. Cancelled
- 2. Rejected
- 3. Cancelled
- 4. Rejected
- 5. Rejected

The claims on appeal are claims 2, 4, and 5.

II.GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claims 2, 4 and 5 comply with the written description requirement of 35 U.S.C. 112, first paragraph.

III. Argument

A. Issues Presented In The Reply Brief

The Examiner's Answer mailed December 8, 2008 raises a number of issues, both factual and legal, relating to the disposition of this case. Each of these issues is listed below as follows:

- 1. Whether the Examiner erred in rejecting Claims 2, 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description.
- Whether the Examiner erred in stating that "Appellants have not defined terms a, b, and c in either the specification or the claims" (Examiner's Answer, page 3, paragraph (9), lines 7 and 8), and that "There is no implicit or express definition of variables a, b, and c" (Examiner's Answer, page 4, line 1).
- 3. Whether the Examiner erred in concluding that numerical values of a, b, and/or c are required for Appellants to have full support of the working examples and "In the absence of a working definition for these terms, Appellant's appear to only have support for the working examples of the specification (Examples 1-3)" (Examiner's Answer, page 3, paragraph 9, lines 8-12).
- 4. Whether the Examiner erred in stating that "The teaching that a, b, and c are represented by numbers does not satisfy the written description requirement" (Examiner's Answer, page 4, lines 11 and 12).
- 5. Whether the Examiner erred in failing to give the words of the claims in issue their plain meaning.

- 6. Whether the Examiner erred in attempting to import limitations from the specification into the claims.
- 7. Whether the Examiner erred in failing to recognize that applicants' specification and claims rebutted the presumption that subscripts a, b, and c are to be given their ordinary and customary meaning by clearly setting forth a definition of those terms that is different from its ordinary and customary meaning.
- 8. Whether the Examiner erred in failing to set forth an express finding of fact why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.
- 9. Whether the Examiner erred in failing to present by a preponderance of the evidence reasons why a person skilled in the art would not recognize in applicants' disclosure a description of the invention defined by the claims.

It is respectfully urged that the answer to each of these nine issues is in the affirmative.

B. The Law

The words of a claim must be given their plain meaning unless such meaning is inconsistent with the specification (MPEP 2111.01, and *In re Zletz*, 893 Fed 2d 319, 321, 13 USPQ 2d, 1320, 1322 (Fed. Cir. 1989). The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ 2d 1321, (Fed.Cir. 2005), en banc.

The ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the remainder of the specification, the prosecution history, extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. *Phillips v. AWH Corp.*, supra at 1327. An applicant is entitled to be his or her own lexicographer, and may rebut the presumption that claimed terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from their ordinary and customary meaning. MPEP 2111.01 IV, and *In re Paulsen*, 30 F. 3d 1475, 31 USPQ 2d 1671, (Fed.Cir. 1994).

An inventor may define specific terms used to describe an invention, but must do so with reasonable clarity, deliberateness and precision and, if done, must set out this uncommon definition in some manner within the patent disclosure so as to give one ordinary skill in the art notice of the change in meaning. See *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d, 1384, 21 USPQ 2d 1383, (Fed. Cir. 1992).

Where an explicit definition is provided by the applicant or a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries*, *Inc.*, 199 F.3d 1295, 53 USPQ 2d, 1065 (Fed.Cir. 1999).

The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure the invention defined by the claims. MPEP, 2163.04, and *In re Wertheim*, 541 F.2d, 191 USPQ 90 (CCPA 1976). The legal standard for determining compliance with the written description requirement is the fundamental factual inquiry of whether the specification conveys with reasonable clarity to those

skilled in the art that as of the filing date sought, applicant was in possession of the invention as now claimed. MPEP 2163.02, and *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ 2d 1111, (Fed.Cir. 1991).

In rejecting a claim for lack of adequate written description, the Examiner must set forth express findings of fact regarding the Examiner's analysis which supports the lack of written description conclusion. Unless or until sufficient evidence or reasoning to the contrary has been presented to the Examiner to rebut the presumption, a description as filed is presumed to be adequate. To rebut this presumption, the Examiner must provide reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was not in possession of the invention as claimed in view of the disclosure of the application as filed.

MPEP 2163

C. Arguments With Respect To Each Of The Above Issues

In the claims in issue, the polysiloxane is defined in the simplest terms. The molecular structure of the polysiloxane is set forth using a combination of chemical symbols expressing the composition by the kind of elements and number of atoms, where appropriate. In the molecular structure, lines joining the atoms are used to represent chemical bonds.

In these molecular structures curved brackets have a subscript n which denotes a specified range of integers. Also, some square brackets have a subscript m which denotes a specified range of integers. Other square brackets are used to define repeating units, and subscripts a, b,

and c are used with these other square brackets to define and differentiate each of these repeating units.

The claims on appeal are narrower than the original claims because the original claims have been amended to require that subscripts a, b and c denote constituent units of the polysiloxane molecular structure. All of the claims in issue indicate that these subscripts a, b, and c denote constitutent units of the polysiloxane.

The specification on page 13, lines 8-15, provides as follows:

"Also, a, b, and c denote constitutent units of the polysiloxane, that is, the polymer has a units, b units, and c units. Other constitutent units may be contained in addition to polymers composed only of a units and b units and polymers composed only of a units, b units, and c units. Also, a units, b units, and c units may either be arranged in a random fashion or in blocks."

It is therefore respectfully submitted that the plain meaning of the specification and claims with respect to a, b, and c is that these letters when used as subscripts on bracketed portions of the polysiloxane polymer represent and define the bracketed structure as denoting constitutent units of the polysiloxane.

It is respectfully submitted that the molecular structure of the claimed polysiloxane is not inconsistent with the standards applied by either the International Union of Pure and Applied Chemistry (IUPAC) or the American Chemical Society (ACS). Importantly, the Examiner has presented no evidence that the molecular structure of the claimed polysiloxane is either indefinite, vague, or unconventional.

It is respectfully submitted that one of ordinary skill in the art would understand that if a, b, and c are represented by integers as contended by the Examiner, the number of repeating constituent units a, b, and c as well as the molecular weight of the polysiloxane polymer would be limited.

However, the specification provides on page 11, lines 15-18, that:

"There is no limitation in terms of the molecular weight of the amino-modified polysiloxane; polysiloxane of any molecular weight can be used." (emphasis ours)

However, as pointed out above, the specification clearly and unequivocally indicates that a polysiloxane of any molecular weight can be used. Therefore, one of ordinary skill in the art, it is submitted, would not attempt to limit the molecular weight of the polysiloxane by limiting the number of repeating constituent units in the polymer as suggested by the Examiner.

The Examiner's understanding of applicants' disclosure appears to be erroneous concerning the definitions of a, b, and c. The specification points out on page 13, lines 16-18, that:

"When a, b, and c are represented by numbers, they denote molar ratios (polymer composition) of the corresponding constituent units."

Such molar ratios of a, b, and c are illustrated in the Examples. In Example 1, page 20, lines 20 and 21 of the specification, provide:

$$a:b=50:1$$

In Example 2 it is indicated on page 21, line 20, of the specification that:

a:b:c is unknown

In Example 3 there is indicated on page 22, line 12, of the specification that:

Considering the applicants' disclosure that (1) the molecular weight of the polysiloxane is not limited and (2) when a, b, and c are represented by numbers, they denote the molar ratio of those constituents. It is strongly urged that one of ordinary skill in the polymer art would recognize that the inventors never intended to limit the molecular weight of the polysiloxane by assigning integers as definitions for the repeating units a, b, and c. In fact, it would be inconsistent to do so considering applicants' intent to broadly claim these particular polysiloxanes.

It would thus appear that the Examiner is attempting to import limitations into the claims. However, the Examiner's intent is contrary to the law set forth above since the specification indicates that any molecular weight of polysiloxane can be used.

Although the letters n and m used as subscripts represent integers, the applicants rebutted the presumption that the terms a, b, and c represent integers. Instead, the specification clearly sets forth a different definition for a, b, and c, and there is no reason whatever why one of ordinary skill in the art would give a different meaning to a, b, and c. Therefore, under the controlling authorities set forth above, the subscripts a, b, and c must be strictly interpreted according to the definitions in the specification and claims.

At no time has the Examiner presented by a preponderance of the evidence any reason why a person skilled in the art would not recognize an applicant's disclosure a description of the invention as now defined by the claims in issue. For these reasons, it is respectfully submitted that the Examiner has erred in construing the terms of the claims, and that the Examiner's

interpretation of the claims is contrary to the plain and ordinary meaning set forth in the specification.

It should be noted that the corresponding Japanese patent application serial No. 2002-340319 was allowed, and issued as Japanese patent No. 4245336 on January 16, 2009.

D. Conclusion

The Examiner erred in concluding that applicants have not defined terms a, b, and c in either the specification or claims. The Examiner also erred in stating that there is no implicit or express definition of a, b, and c.

Also, the Examiner erred in attempting to read into the claims in issue numbers for the constitutent units a, b, and c, contrary to well-established legal principles. Further, the Examiner erred in failing to interpret the meaning of a, b, and c in light of the specification, in particular, the teaching that the molecular weight of the polysiloxane was not limited, and that the numbers for a, b, and c referred to are only used in connection with the molar ratios between a, b, and c. That is, integers are not used to define the number of repeating units in the polymer, but only the molar ratios of the repeating units.

Additionally, the Examiner has failed to present by a preponderance of the evidence reasons why a person skilled in the art would not recognize in applicants' disclosure, a description of the invention defined by the claims.

Clearly, the Examiner's insistence on assigning integers to a, b, and c is entirely unwarranted and contrary to the description of the invention as a whole, particularly, the teaching that the

molecular weight of the polysiloxane is not limited. For all of the above reasons, the Examiner

erred in rejecting Claims 2, 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply

with the written description. Therefore, the rejection should be overruled and the case passed to

issue.

Respectfully submitted,

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